From: **gibson, aleisia (GE Healthcare)** [redacted]
Date: Wed, Mar 6, 2013 at 3:47 PM
Subject: Omniscan
To: "jeff.gerth[redacted]" [redacted]

Hi Jeff,

Thanks for your time on the phone today. Per our conversation, I have enclosed our key points for your consideration and inclusion. Re: number of cases - we do not want to discuss specific numbers but if you wrote several hundred we'd be fine with that.

- The benefits of Omniscan far exceed the risks for the vast majority of patients.
- We turned over all of the relevant information to regulators and the info was published in medical literature. From the beginning, the regulators and the medical community were aware of potential risks from GBCAs in people with damaged kidneys. But this evidence could in no way be considered a signal for NSF - a then unknown disease.

- Part of the reason NSF was not foreseeable is because it is very rare. Of people who receive GBCAs, 99.9998% do not get NSF. Omniscan has been used effectively for more than 17 years in more than 47 million doses to enable physicians to detect life-threatening conditions despite more than 20 years of clinical experience with millions of patients.
- Once this issue was discovered by the medical community, GE acted swiftly and responsibly and in coordination with the FDA and global regulatory agencies, and was the only GBCA manufacturers to do so.

- After first learning about a potential link between GBCAs and NSF in 2006, GE Healthcare was the first manufacturer in the industry to work with global regulatory authorities to proactively inform

healthcare providers and patients of the potential risk of NSF for patients with kidney disease. Once the link between Omniscan and NSF was suggested, the GE Healthcare team reached out to discover more information about the issue, discussed the health risks with regulatory officials around the world, and notified health professionals of those potential risks.

- GE Healthcare's actions after the discovery of the potential NSF-GBCA link: After the suggestion of a NSF-GBCA link, GE Healthcare took prompt action to address the issue. The company asked the DMA for information about possible Danish cases in March, commenced a period of almost daily contact with the FDA starting in April, and issued a "Dear Healthcare Provider" letter in June. GE Healthcare worked with FDA in 2006 and early 2007 as FDA evaluated the incoming data regarding NSF and all GBCAs. After FDA decided a boxed warning was required for all GBCAs, GE Healthcare implemented the new labeling.

- GE Healthcare has continued to conduct and sponsor research into how NSF may develop in patients with kidney disease. These research efforts continue to the present day.

- There are no confirmed reports of NSF associated with the administration of Omniscan occurring after 2007.

I'm around to answer any further questions. [redacted]

Thank you,

Aleisia